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Food and Drug Administration
Dockets Management Branch (HFA-305)
Department of Health and Human Services
Room 1-46
12420 Parklawn Drive
Rockville, MD 20857

CITIZEN PETITION

The undersigned submits this petition as outlined in Section 510(g) of the Federal Food, Drug and Cosmetic Act and Section 821.2 of Title 21 of the Code of Federal Regulations.

This petition requests that the Commissioner of Food and Drugs (a) review and amend, and/or (b) grant exemptions from certain requirements of Title 21 Code of Federal Regulations to those enterprises engaged in the e-commerce distribution of products regulated by the Food and Drug Administration. This petition also requests that the Commissioner of Food and Drugs grant exemptions from these certain requirements of Title 21 Code of Federal Regulations to two divisions of Ventro Corporation, Chemdex Corporation ("Chemdex") and Promedix, Inc. ("Promedix"). Both Chemdex Corporation and Promedix, Inc. intend to engage in, or are engaged in, the e-commerce of products regulated by FDA.

Ventro Corporation believes that certain requirements regulating the commerce of food, drug products, biologics, and medical devices are not applicable to e-commerce business transactions mediated by a company, such as Chemdex or Promedix, whose primary function is to bring buyer and seller together on the Internet and facilitate the sale and purchase of certain products. This function of serving as a facilitator of the business transaction is usually defined in the regulations variously as that of a "broker," an "agent." or a "distributor," depending on certain specifics of the transaction, or the product family that is being regulated. The requirements that Ventro Corporation believes are not applicable to e-commerce companies operating under the Ventro Corporation business model (Chemdex, Promedix) include regulations concerning the registration, record keeping, reports, and the tracking of certain regulated products. In many instances, the current requirements would generate reports and records that are duplicative of other reports and records that are generated and provided to the Food and Drug Administration.

Ventro Corporation recognizes that many of the regulations, and the definitions within these regulations, were generated before the advent of e-commerce (commonly referred to as the "Internet") and of business-to-business ("b2b") transactions. It is in a spirit of cooperative understanding, education, and modernization that this petition is submitted.

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I. Action Requested

This petition requests that the Commissioner of Food and Drugs (a) review and amend, and/or (b) grant exemptions from certain requirements of Title 21 Code of Federal Regulations to those enterprises engaged in the e-commerce distribution of products regulated by the Food and Drug Administration. This petition also requests that the Commissioner of Food and Drugs grant exemptions from these certain requirements of Title 21 Code of Federal Regulations to two divisions of Ventro Corporation, Chemdex Corporation ("Chemdex") and Promedix, Inc. ("Promedix"). Both Chemdex and Promedix intend to engage in, or are engaged in, the e-commerce of products regulated by FDA.

Ventro Corporation is requesting that the Commissioner of Food and Drugs review FDA regulations regarding the responsibilities of a distributor with regard to registration, record keeping, reports, and tracking and grant its Chemdex and Promedix divisions (both e-commerce business-to-business (b2b) companies), an exemption from the FDA requirements for registration, record keeping, reports, and device tracking, as required for a distributor of FDA-regulated products.

II. Existing Regulations

Chemdex and Promedix propose to offer for sale several products that are regulated by FDA. The types of products proposed for sale include foods and dietary supplements, pharmaceuticals, diagnostic radiopharmaceuticals, over-the-counter drugs, biologics, in vitro diagnostics, analyte specific reagents, medical devices, electronic products, and controlled substances. The regulations specific to each of these product families indicate the degrees of compliance that is required.

The role that Chemdex and Promedix play in such Internet transactions between buyers and sellers has been called that of a "facilitator." In the "bricks and mortar" type of business enterprise the function might be best described as a distributor---although other names can be ascribed to this function. For the purposes of this petition, Ventro has reviewed the FDA regulations for a number of product families and has found that the definition of "distributor" found in Title 21 of the Code of Federal Regulations ("21 CFR") most closely approximates the function that is performed by Chemdex and Promedix. Hence, "distributor" will be the term that is used to describe the function and service provided by Chemdex and Promedix. Ventro recognizes that the Commissioner may not agree that the definition of "distributor" accurately describes the function and services provided by Chemdex and Promedix.

The current regulations relevant to this petition are listed below.

A. Exemptions:

The current regulations provide for the request for exemption from certain regulations governing FDA-regulated products Section 510(g) of the Federal Food, Drug, and Cosmetic Act (the "Act" in this petition). Provisions for exemption are also specified in the regulations pertaining to pharmaceutical drugs and to medical devices, but not for other product families regulated by FDA. Exhibit I summarizes the current regulations.

B. Registration:

The current regulations governing the registration of distributors of FDA-regulated products are summarized in Exhibit II. Various definitions are also provided in this exhibit for "distributors," "agents," and "dealers"--each of which may appear applicable to the Chemdex and Promedix business models.

C. Medical Device Reporting:

The current regulations governing the reporting by distributors of adverse events are summarized in Exhibit III. There are specific requirements for pharmaceuticals, biologics, and medical devices.

Recent changes have been made to the regulations as a consequence of the FDA Modernization Act of 1997 ("FDAMA"): Part 804 of 21 CFR has been deleted to remove the requirement for medical device reporting by distributors of medical devices. Whereas distributors are no longer required to file Form 3500A with the FDA they are still required to maintain "complaint" (or "adverse event") files that can be reviewed by FDA personnel as required, or can be provided to manufacturers as needed.

D. Medical Device Tracking:

The current regulations for distributors governing the tracking of medical devices are summarized in Exhibit IV. Recent FDAMA regulations have reduced the types of devices that require tracking, however, the requirement for the distributor to provide information back to the manufacturer remains in the current regulations.

D. Records and Reports:

Current regulations require certain types of record keeping in addition to those discussed above. Most of these regulations require the maintenance of inventory and/or transaction records for FDA-regulated products. These regulations are summarized in Exhibit V.

III. Statement of Grounds

A. Introduction

Ventro Corporation ("Ventro") is seeking exemption from the Commissioner of Food and Drugs for two of its divisions, Chemdex and Promedix. Ventro is seeking exemption from the registration, reporting, record keeping, and tracking requirements, as described in the current regulations, for products regulated by FDA.

This request for exemption is not motivated to avoid the registration and record keeping requirements of the FDA but because Ventro Corporation believes that Chemdex (and Promedix) registration, reporting, tracking, and record keeping would be duplicative of other registration, record keeping, and reporting already being maintained for the same transactions. Furthermore, in the spirit of Section 510(g) of the Federal Food, Drug and Cosmetic Act, Ventro believes that such duplicative registration and record keeping requirements are not necessary for the protection of the public health.

The business models for both Chemdex and for Promedix are identical. For the purposes of this document, a description of Chemdex processes will be presented, but it should be noted that the identical processes also occur in the Promedix model. Any differences between the Chemdex process and the Promedix process will be noted as they are presented.

B. Business Model

1. *The Chemdex Marketplace facilitates the availability and the purchase of products but does not physically warehouse or ship such products.*

   This business model positions Chemdex as a "provider" or a "facilitator" for a wide variety of products rather than as the classical distributor of goods with physical inventory under its control.

   For clarification, neither Promedix nor Chemdex manufacture, or otherwise further process, any of these products but simply offers them for sale online.

   Some of the products that we propose to offer are regulated by the FDA, including but not limited to, foods and dietary supplements, pharmaceuticals and controlled substances, over-the-counter drugs, biologics, in vitro diagnostic products, medical devices, and electronic products.

2. *The Chemdex business transaction occurs online (www.chemdex.com; for Promedix: www.promedix.com).*

   The normal process for a business transaction via each website is as follows:

   (a) Customer logs onto the website and places order for specific items on the website,
   (b) Chemdex acknowledges and verifies order with customer,
   (c) Chemdex forwards the order to the specific supplier(s) of the items ordered,
   (d) Supplier receives order from Chemdex,
   (e) *If applicable, supplier requests any appropriate user permit/license information from customer (via Chemdex) and supplier maintains any records that may be necessary,*
   (f) Supplier fills the customer order from his inventory,
   (g) Supplier ships order directly to the customer,

(h) Chemdex bills the customer directly for the items ordered,
(i) Customer pays for the items on the Chemdex invoice, and
(j) Chemdex pays the supplier for the items shipped to the customer.

3. *The online business transaction differs from the classical distributor transaction.*

There are some aspects of the Chemdex e-commerce transactions that should be noted, and which distinguish, this transaction from the usual traditional business transaction of a distributor: The same aspects are applicable to the Promedix e-commerce transaction as well.

(a) Chemdex does not maintain any warehousing of any of the products offered for sale. All warehousing is maintained at the individual suppliers and remains under their control.

(b) Promedix does not take physical possession of the products during the transaction.

(c) For some products, Chemdex does take legal title of the goods for accounting and billing purposes.

(d) For some products ("consignment products"), Chemdex does not take legal title of the goods. For these products Chemdex acts as an agent of the supplier.

(e) For those products that Promedix takes legal title, the customer receives an invoice for the products from Promedix, rather than from the supplier/shipper of the products. For consignment products, the customer receives an invoice from the supplier.

(f) The product is shipped directly from the supplier to the customer. The product is not shipped to any intermediate warehousing site other than those under the control of the supplier.

C. Company Overviews

1. Chemdex is an internet-based provider of life science products.

Chemdex Corporation is a leading provider of e-commerce solutions to the life sciences industry. The company website allows life sciences enterprises, researchers, and suppliers to efficiently buy and sell chemical and biological products through the Chemdex Marketplace (www.chemdex.com), a secure, internet-based purchasing solution. The Chemdex Marketplace allows users to identify, locate, and purchase life science products from a database of approximately 1.7 million products from approximately 2200 suppliers. The company attracts suppliers by providing them with a marketplace to reach new customers. In turn, Chemdex suppliers pay Chemdex a transaction fee for listing and selling their products.

2. Promedix.com is an internet-based provider of specialty medical products.

Promedix is a leading provider of e-commerce solutions to the specialty medical supplies industry. Promedix enables physicians, other medical professionals, hospitals and suppliers to efficiently buy and sell specialty medical products through the Promedix Marketplace (www.Promedix.com), a secure, internet-based purchasing solution. The Promedix Marketplace allows users to identify, locate, and purchase specialty medical products from a

database of approximately 220,000 products from approximately 200 suppliers. Promedix attracts suppliers by providing them with a marketplace to reach new customers. In turn, Promedix suppliers pay Promedix a transaction fee for listing and selling their products.

D. FDA-Regulated Products

1. *Chemdex offers a variety of life science products to its customers.*

Chemdex proposes to offer its products for sale to life science enterprises, researchers, universities and medical centers and other facilities where basic and applied research takes place. A list of the major categories of FDA-regulated products that will be offered is provided in Table 1.

Table 1. Proposed FDA-Regulated Materials on Chemdex Website
Diagnostic Radiopharmaceuticals
Animal Drugs
Biologics
In Vitro Diagnostic Products
Analyte Specific Reagents
Controlled Substances and Listed Chemicals
Organisms, Vectors, Toxins

2. *Promedix offers a variety of specialty medical products to its customers.*

Promedix proposes to offer for sale its products to American hospitals, medical centers, medical clinics, urgent care centers, physicians' offices, and other facilities where healthcare is provided. A list of the major categories of products that will be offered is provided in Table 2.

Table 2. Proposed FDA-Regulated Products on Promedix Website
Foods
Dietary Supplements
Pharmaceuticals
Diagnostic Radiopharmaceuticals
Orphan Drugs
Over-The-Counter Drugs
Biologics
Medical Devices (Class I, II, and III)
Analyte Specific Reagents
In Vitro Diagnostic Products
Electronic Devices
Controlled Substances

E. Regulatory Compliance

The structure of the Chemdex business model, and the Promedix business model, facilitates the compliance of our suppliers and our customers in several aspects.

(a) Each supplier receives complete customer information (name, address, telephone number, e-mail, etc) at the time of each transaction (see section B.2, above). Hence, Chemdex provides the necessary traceability to each supplier for each transaction by providing the supplier with customer information.

(b) For regulated products requiring registration, licenses, or permits from the purchaser, each supplier verifies such requirements at each transaction and maintains the records of such verification and qualification.

(c) The supplier will not ship regulated product to customers who cannot provide the appropriate end user documentation. Hence, the likelihood that regulated product arrives in the hands of unqualified users is greatly reduced.

(d) The record keeping requirements for both suppliers and end users is clearly defined in the appropriate parts of the Code of Federal Regulations. Hence, the Chemdex role as "facilitator" of the transaction does not alter the conventional regulatory requirements that would be imposed on both supplier and customer if the customer directly contacted the supplier and placed the order.

In addition, Chemdex and Promedix have reviewed the regulatory requirements for suppliers and purchasers from federal, state, and local agencies. These regulatory requirements are reflected in the contractual Agreements that are signed with each supplier, the contractual Agreements that are signed with each purchaser, and in the website "Terms and Conditions" which each purchaser must acknowledge at the time of each transaction. The regulatory

strategy of each of these documents has been to advise the supplier, or purchaser, of the regulatory obligations that may exist for certain products. In addition, these documents also advise the supplier, or purchaser, of his responsibility to be knowledgeable of any regulatory restrictions. Finally, these documents obtain indemnification of Chemdex (or Promedix) from each supplier, or purchaser, in the event that the supplier (or purchaser) fails to meet the regulatory obligations.

1. Supplier Agreement

   Each supplier signs an agreement with Chemdex prior to the appearance of the Supplier's products on the Chemdex website. Section 4 of this agreement outlines the responsibilities of the supplier. Among these responsibilities are those of sections 4.2 through 4.4 which directly address compliance issues, and especially sections 4.3 and 4.4 which address compliance with regard to FDA-regulated products. These portions of the Chemdex Supplier Agreement are quoted in Exhibit VI.

   The Promedix Supplier Agreement also contains sections dealing with regulatory compliance. Sections 4.1 through 4.5 address the various aspects of compliance with a heavy emphasis on compliance to FDA regulations since FDA regulates most of Promedix products. Exhibit VII quotes the relevant sections of the Promedix Agreement.

2. Customer Agreement

   Each enterprise customer signs a Sales Customer Agreement with Chemdex before they begin purchasing products on the website. Section 2 of this agreement outlines the Customer Representations and Warranties. Section 2.1 ("Use Restrictions") calls out for certain restrictions that are imposed on the customer regarding the use of products purchased on the website. Certain federal regulatory agencies are mentioned by name, including USDA, ATF, EPA, and FDA. Section 2.2 ("Compliance with Laws") calls for certain warranties from the customer regarding compliance to "all applicable laws" applicable to the "sale, distribution, transfer, transportation, exportation, importation, handling, disposal, processing or use" of the purchased product. Sections 2.1 and 2.2 are reproduced in Exhibit VIII.

   Section 2.1 mentions Exhibit B ("Regulatory Addendum") of the Agreement. This is part of the Sales Customer Agreement and is a brief summary of some of the federal regulatory requirements that relate to products sold on the Chemdex Marketplace. The Regulatory Addendum also identifies certain restrictions regarding the products sold on the website. In addition, it provides the website for the major agencies that regulate Chemdex products. Exhibit B is reproduced in Exhibit IX.

   The Promedix Sales Customer Agreement has a very similar Section 2 on Customer Representations and Warranties. Section 2.1 ("Use Restrictions") calls out for certain restrictions that are imposed on the customer regarding the use of products purchased on the website. Compliance to FDA restrictions on the use of certain products is called out. Section 2.2 ("Compliance with Laws") calls for certain warranties from the customer regarding compliance to "all applicable laws" applicable to the "sale, distribution, transfer, transportation, exportation, importation, handling, disposal, processing or use" of the purchased product. Sections 2.1 and 2.2 are reproduced in Exhibit X.

Section 2.1 mentions Exhibit B ("Regulatory Addendum") of the Agreement. This is part of the Sales Customer Agreement and is a brief summary of some of the federal regulatory requirements that relate to products sold on the Promedix Marketplace. The Regulatory Addendum also identifies certain restrictions regarding the products sold on the website. In addition, it provides the website for the major agencies that regulate Promedix products. Exhibit B is reproduced in Exhibit XI.

3. Terms and Conditions

In addition to the Sales Customer Agreement, each customer must acknowledge the Chemdex "Terms and Conditions" at the time of each transaction on the website: Prior to placing each order the purchaser is asked in a drop down menu whether he agrees to the Chemdex Terms and Conditions. The purchaser must respond in the affirmative (check box) before the order is accepted.

Paragraph 6 (Use Restrictions) on this website document reiterates the restrictions that appear in the Sales Customer Agreement. The paragraph is reproduced in Exhibit XII.

Paragraph 7 (Compliance with Laws) on this website document reiterates the compliance with all "applicable laws" that appears in the Sales Customer Agreement. The paragraph is reproduced in Exhibit XIII.

Likewise, in addition to the Sales Customer Agreement, each customer must acknowledge the Promedix "Terms and Conditions" at the time of each transaction on the website: Prior to placing each order the purchaser is asked in a drop down menu whether he agrees to the Promedix Terms and Conditions. The purchaser must respond in the affirmative (check box) before the order is accepted.

Paragraph 6 (Use Restrictions) on this website document reiterates the restrictions that appear in the Sales Customer Agreement. The paragraph is reproduced in Exhibit XIV.

Paragraph 7 (Compliance with Laws) on this website document reiterates the compliance with all "applicable laws" that appears in the Sales Customer Agreement. The paragraph is reproduced in Exhibit XV.

F. FDA Review of the Ventro Corporation Petition

Ventro Corporation believes that the basis of this petition is whether or not Internet providers of FDA-regulated products meet the definition of "distributor" that is used by FDA. If they do meet the definition, are they exempt from all the registration, record keeping, reporting, and tracking requirements? If they do not meet the definition, what is the definition that is applicable and what are the requirements of this definition regarding registration, record keeping, reporting, and tracking requirements?

Ventro is seeking exemption for our Chemdex and Promedix divisions from the registration, tracking, reporting and record keeping requirements for all FDA-regulated products. Ventro believes that FDA should use one set of criteria in evaluating this petition regardless of the specific regulations for any individual FDA-regulated product families (e.g., drugs and devices).

Ventro believes that FDA review of this petition will involve consideration of the following factors:

1. Does the broker take physical possession of the product during the transaction?
2. Does the broker take legal possession of the product during the transaction?
3. Does the broker meet the definition of "wholesale distributor" as that term is used in the Federal Food, Drug, and Cosmetic Act?
4. If the broker does not meet the definition of "wholesale distributor," how is the function of the broker to be defined?
5. Are the records generated by the broker necessary for product traceability?
6. Is regulation of Internet brokers by FDA necessary for the protection of the public health?

Review of the above issues and the resolution of this petition would enable FDA to make the following conclusions and grant the following exemptions:

1. **Internet brokers of FDA-regulated products do not meet the definition of "wholesale distributor" [section 510(g)(4) of the Act] and hence the regulations pertaining to wholesale distributors are not applicable to Internet brokers. Since Internet brokers of FDA-regulated products do not meet the definition of "wholesale distributor," they are exempt from the registration, record keeping, reporting, and tracking requirements for FDA-regulated products.**

   FDA may conclude that the function and responsibilities of Internet companies such as Chemdex and Promedix is sufficiently different from that of a "wholesale distributor" to warrant a separate designation by FDA. Hence, Internet companies would be distinguished from the existing definitions of "wholesale distributor," or from other similar designations. The exclusion of Internet brokers from the current definitions (e.g., wholesale distributor, dealer, broker, and agent) would require that a definition be provided for such brokers.

   Ventro Corporation has assumed in this petition that the function provided by Chemdex or Promedix most closely approximates the FDA regulatory definition of a wholesale distributor, but other alternatives could be considered as has been demonstrated by other federal agencies (e.g., "dealer," "broker," "agent"; see Exhibit XVI).

   Should FDA decide that the current regulatory definition is not adequate or appropriate, Ventro believes that the term "Internet broker" might describe the service provided by Internet Marketplaces such as Chemdex and Promedix. Whether such "Internet brokers" should then be included in the definition of wholesale distributor is an issue that needs to be resolved by FDA.

   The potential difficulty with including such Internet brokers under the classical definition of distributor (or agent, or dealer) is that these Internet companies do not meet the definition of a distributor as that term has been used for the traditional "bricks and mortar" types of companies. That is, the classical and historical definition of a distributor assumes that physical and legal possession and warehousing of the product occurs at the distributor. In the Ventro business models outlined above in section B, no physical possession or warehousing of the products ever occurs.

   In some transactions, legal possession of the products does occur. In such instances, Chemdex (or Promedix) assumes all responsibility for the product for the specified interval, namely, from the time the product leaves the shipping dock of the supplier to the time the product arrives at the receiving dock of the customer. An outstanding issue that needs resolution is whether legal ownership constitutes "possession," as that term is commonly used.

In other transactions, neither physical nor legal possession (e.g. consignment products, see section B.3 (d), above) takes place but Chemdex (or Promedix) merely acts as the agent of the supplier in exchange for a fee. In such instances the supplier assumes responsibility for the product from the time the product leaves the shipping dock of the supplier to the time the product arrives at the receiving dock of the customer.

2. Internet brokers of FDA-regulated products meet the definition of "wholesale distributor" [section 510(g)94) of the Act]. Since Internet brokers of FDA-regulated products meet the definition of "wholesale distributor," they are exempt from the registration, record keeping, reporting, and tracking requirements for FDA-regulated products.

Section 510(g)(4) of the Federal Food, Drug and Cosmetic Act specifically calls out medical devices in its definition of wholesale distributor. However, Ventro believes that this definition describes the Chemdex and Promedix business models for all FDA-regulated products. If this definition is applied to the other product families regulated by FDA, Chemdex and Promedix would be exempt from the registration requirements of 21 CFR because they are wholesale distributors of FDA-regulated products.

Section 213(a) of the FDA Modernization Act of 1997 removed the requirement for medical device distributors to submit adverse event reports to FDA. Furthermore, Part 804 (Title 21 Code of Federal Regulations) was removed by the FDA on January 26, 2000 (Federal Register/Vol. 65. No.17, page 4112).

Ventro Corporation acknowledges the requirement cited in 21 CFR 803.19(d) that Chemdex and Promedix "maintain device complaint records." However, it is proposed that the sole responsibility that Internet brokers like Promedix and Chemdex shall have regarding such complaint records is to provide the manufacturer with the name, address and other contact information for the source of the complaint. The responsibility for the report would belong to the manufacturer as described in 21 CFR 803.50.

With regard to medical device tracking requirements, Promedix and Chemdex are distributors of medical devices as that term is defined in 21 CFR 821.3(h):

(a) Chemdex does further the distribution of a medical device from the original place of manufacture to the person who makes delivery or sale to the ultimate user,

(b) Chemdex does not repackage or other wise change the container, wrapper, or labeling of the device or device package, and

(c) Chemdex is not the final distributor of any medical devices, as that term is defined in 21 CFR 821.3(l).

The standard operating procedure for all transactions (taking legal title or acting as agent) includes the notification to the supplier to ship the device to the purchaser (see section B.2, above):

(a) Promedix accepts the order for the device from the purchaser and then notifies the supplier of the name and shipping address of the purchaser, and
(b) The supplier ships the device directly to the purchaser.

3. Internet brokers of FDA-regulated products meet the definition of "wholesale distributor" [section 510(g)(4) of the Act] whenever such companies take possession of the product.

The central issue here is what constitutes possession of the product. If taking legal possession of the product (and hence assuming responsibility for the product for a certain period of time) is the criterion, then it would appear reasonable that such companies be designated as distributors. If taking physical possession of the product (and hence assuming responsibility for the product for a certain period of time) is the criterion, then it can be concluded that companies such as Chemdex and Promedix, who do not take physical possession, do not meet the criterion. If possession includes both legal and physical possession, companies such as Chemdex and Promedix do not meet the criterion.

In some transactions, Chemdex (and Promedix) do not take legal title to the products and merely act as agent for the supplier. In such transactions, Chemdex (and Promedix) serves as a broker [as that term is defined in 21 CFR 821.3(b)] for these Internet transactions because it "only performs a service for the person who furthers the marketing, i.e., brokers, jobbers, or warehousers." Clearly, the supplier furthers the marketing of the product by engaging Chemdex (or Promedix) to list his products on the website. Because the supplier retains legal title for the products, Chemdex (or Promedix) are agents for the supplier.

IV. Opposing & Unfavorable Views

Ventro Corporation believes that it has presented sufficient evidence for the requested exemptions. However, contrary views and decisions can be reached from the evidence and arguments presented here.

On behalf of Chemdex, other regulatory agencies have been solicited for exemption(s) from their regulations. The basis for all requests for exemption was the same: Chemdex does not take physical possession of the product (although it does take legal title) and hence should be exempt from the requirements for registration and record keeping.

In some instances, the decisions reached by these agencies support and strengthen the present arguments but in other instances, the decisions that have been reached present an unfavorable view of the present arguments.

1. Radiologic Health Branch, California Department of Health Services

California is an Agreement State with the Nuclear Regulatory Commission (NRC). As an Agreement State, the regulatory compliance regarding radioactive materials has been delegated to the Radiologic Health Branch of the California Department of Health Services (RHB). The regulations for radioactive materials are contained in Title 17 of the California Code of Regulations (CCR), Chapter 5, subchapter 4: California Radiation Control Law.

Chemdex sought clarification from the state agency regarding its requirements to obtain registration with RHB. Specifically, Chemdex was requesting exemption from the registration and record keeping requirements of RHB because Chemdex does not take physical possession of any radioactive materials during the transaction.

RHB advised Chemdex that since it takes legal title to the material, this is considered "ownership" of the material, and hence, Chemdex is required to obtain a radioactive materials license. On the other hand, RHB advised Chemdex that if Chemdex does not take title to the material, and merely acts as the agent of the supplier, Chemdex is not required to meet the license and record keeping requirement of CCR Title 17, Chapter 5, subchapter 4.

Based on this decision by RHB, Chemdex has revised its plans to provide radioactive materials to its customers so that Chemdex does not take title to radioactive materials. The Supplier Agreement with each supplier of radioactive materials specifically identifies Chemdex "to act as the Supplier's agent on the Chemdex System." The supplier pays Chemdex a monthly "Agent Fee."

2. Drug Enforcement Administration

Chemdex sought clarification from the Drug Enforcement Administration of the Department of Justice regarding its registration and record keeping requirements for "distributors." Chemdex was requesting exemption from the registration and record keeping requirements of DEA because Chemdex does not take physical possession of any controlled substance (Schedules I-V) or List I chemicals during the transaction (There are no registration requirements for List II chemicals). In addition, Chemdex sought a similar exemption on similar grounds for DEA-regulated materials for importation and exportation.

DEA responded to the request for exemption in two parts: one based on the controlled substances; the other based on the List I chemicals:

(a) Controlled Substances:

DEA stated that "DEA does not issue registrations to firms acting as brokers for controlled substances if the firm does not take physical possession of the controlled substances. Since a DEA controlled substance registration is not necessary, there is no need for an exemption." With regard to importation and exportation, DEA goes on to states "for controlled substances, registration is not required since Chemdex will not be taking physical possession of these products."

(b) List I Chemicals:

With regard to List I chemicals, DEA has stated "The registration requirements in regard to the sale of List I chemicals by an Internet broker differ from those fort controlled substance brokers. Activities involving List I chemicals that require registration include the 'constructive transfer' of List I chemicals, as opposed to the physical distribution of controlled substances." In view of the fact that Chemdex would bill the customer on a Chemdex invoice and would take legal title of such List I chemicals, DEA has stated that "these activities fall within the definition of 'constructive transfer,' and therefore require registration as a non-retail distributor." The registration requirement would also apply to the importation and exportation of List I chemicals according to DEA because "chemical importers and exporters are defined in the regulation as the principal party of interest in the transaction who has the power and responsibility for determining and controlling the sending of the chemical either into or out of the United States. 21 CFR 1300.02(b)(6) and (b)(8). Since Chemdex will be the party directing the sending of a List I chemical into or out of the United States, the registration requirement would apply."

The DEA decisions reflect two criteria that were used selectively in determining the registration and record keeping requirements, regardless of the same Chemdex process that occurs for both types of transactions: (a) physical possession, and (b) constructive transfer. In the case controlled substances, the primary requirement for registration is physical possession (see 21 CFR 1301.11 and 1301.12(b)(2))---and since that does not occur there is no requirement for registration. The regulations for List I chemicals differ slightly from those for controlled substances with two notable differences: (a) non-retail distribution of List I chemicals is cited as an activity that requires registration [21CFR 1309.22(a)(2)]; and (b) chemical exporters and importers are defined as "the principal party of interest" [21 CFR 1300.02(b)(6) and (8)] in the importation or exportation of such chemicals. The definitions for exporter and importer supercede the exemption stated in 21 CFR 1309.23(b)(2) for an "office used by agents of a registrant where sales of List I chemicals are solicited, made, or supervised but which neither contains such chemicals...nor serves as a distribution point for filling sales orders."

Chemdex has accepted the DEA decision regarding controlled substances, even though Schedule I-V controlled substances do not appear on the Chemdex website at the present time. It is expected that these will be available shortly.

Chemdex is currently evaluating the DEA decision regarding List I chemicals. Chemdex may apply for registration as a non-retail distributor for such materials in order to retain legal title to these materials. Alternatively, Chemdex may waive legal title to List I chemicals to preclude the registration requirement. Instead, Chemdex would serve as the agent of the supplier for such transactions. A final decision between these two alternatives has not been made at the present time.

3. Bureau of Alcohol, Tobacco, and Firearms

Chemdex desires to offer two product families that are regulated by the Bureau of Alcohol, Tobacco, and Firearms (ATF) of the Treasury Department, namely, alcohols and certain chemicals that are designated as explosives by ATF. Two separate branches of ATF regulate these products by the issue of permits and licenses, as well as certain taxation. Chemdex requested clarification of the regulations and requested exemptions from each branch of ATF.

(a) Alcohols

The alcohol branch of ATF responded quickly and favorably to our queries regarding the sale of various alcohols and the regulations that Chemdex must comply with. The ATF decision regarding Chemdex sales falls within the Chemdex business model and will not require a permit or special taxation:

(i) Specially denatured alcohols (SDA) will be available to Chemdex customers. The "use restriction" and "compliance with Laws" sections of our customer agreement (and the Terms & Conditions page on our website; see Exhibit VIII and IX)) advise purchasers of the "research use only" restriction as well as the need for certain licenses and permits.
(ii) All ethanol sales are also restricted to "research use only" and constitute industrial uses.
(iii) Reagent alcohol is offered for sale and in compliance with 27 CFR 20.117.
(iv) Chemdex will not import any alcohols for beverage use or for re-sale.

(b) Explosives

The explosives branch of ATF has proceeded in a slightly different direction regarding our inquiries and request for exemption. They instructed Chemdex to submit the request for an exemption along with the standard registration application (ATF 5400.13). The registration application has undergone review for the past several months and no decision has been reached to date. According to ATF, a final decision will be made before the end of 2000.

V. Concluding Comments

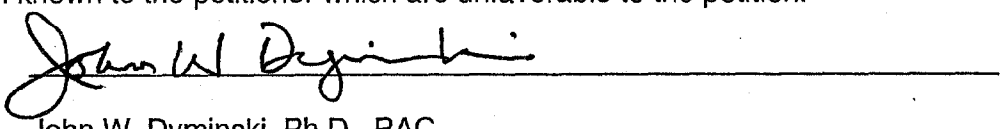
Ventro is anxious to be in compliance with the requirements of the Food and Drug Administration but feels that it would be in the best interests of the Administration, and of both of Ventro's divisions (Chemdex, Promedix) to avoid duplicative reports and registrations. Promedix Corporation is very interested in the view of the Administration on these matters, and specifically, on the matter of our request for exemption from the regulations cited above. Your prompt response to the above issues will facilitate our compliance to the regulations prior to any sales.

VI. Environmental Impact

Ventro Corporation has determined under 21 CFR 25.30(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Signature 

Name John W. Dyminski, Ph.D., RAC

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E Mail jdyminski@chemdex.com

Exhibit I: Existing Regulations, Exemptions

Reference*	Regulation
Section 510(g)	The foregoing subsections of this section shall not apply to...such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that registration by such classes of persons in accordance with this section is not necessary for the protection of the public health.
21 CFR 207.10	The following classes of persons are exempt from registration and drug listing in accordance with this part under section 510(g) (1), (2), and (3) of the act, or because FDA has found, under section 510(g)(4), that their registration is not necessary for the protection of the public health.
21 CFR 821.2(a)	A manufacturer, importer, or distributor may seek an exemption or variance from one or more requirements of this part.

*Reference is to the Federal Food, Drug and Cosmetic Act (by "Section") or to Code of Federal Regulations ("CFR")

Exhibit II: Existing Regulations, Registration

Reference*	Regulation or Definition
Section 510(b)	...every person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs or a device or devices shall register with the Secretary...
Section 510(c)	Every person upon first engaging in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs or a device or devices in any establishment which he owns or operates in any State shall immediately register with the Secretary...
Section 510(g)	The foregoing subsections of this section shall not apply to... (4) any distributor who acts as a wholesale distributor of devices, and who does not manufacture, repackage, process, or relabel a device; or (5) such other classes of persons as the Secretary may by regulation exempt from the application of this section upon a finding that registration by such classes of persons in accordance with this section is not necessary for the protection of the public health. In this subsection, the term "wholesale distributor" means any person (other than the manufacturer or the initial importer) who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user.
21 CFR 203.3(b)	*Authorized Distributor* of record means a distributor with whom a manufacturer has established an ongoing relationship to distribute such manufacturer's products.
21 CFR203.3(h)	*Distribute* means to sell, offer to sell, deliver, or offer to deliver a drug to a recipient...
21 CFR 205.3(f)	...*wholesale distribution* means distribution of prescription drugs to persons other than a consumer or patient...
21 CFR 205.3(g)	*Wholesale distributor* means anyone engaged in wholesale distribution of prescription drugs, including, but not limited to, manufacturers; re-packers; own-label distributors; jobbers; brokers; warehouses...independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.
21 CFR 600.3(aa)	*Selling agent* or *distributor* means any person engaged in the unrestricted distribution, other than by sale at retail, of products subject to license.
21 CFR 803.3(g)	*Distributor* means, for the purposes of this part, any person (other than the manufacturer or importer) who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user...
21 CFR 807.3(b)	*Commercial distribution* means any distribution of a device intended for human use which is held or offered for sale...
21 CFR 807.3(s)	*Wholesale distributor* means any person (other than the manufacturer or the initial importer) who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user.
21 CFR 807.20(a)	An owner or operator of an establishment...who is engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use is required to register...
21 CFR 807.20(c)	Registration and listing requirements shall not pertain to any person who: ...(3) Acts as a wholesale distributor, as defined in 807.3(s), and who does not manufacture, repackage, process, or relabel a device.

*Reference is to the Federal Food, Drug and Cosmetic Act (by "Section") or to Code of Federal Regulations ("CFR")

Exhibit II: Existing Regulations, Registration (continued)

Reference*	Regulation
21 CFR 1000.3(f)	*Dealer* means a person engaged in the business of offering electronic products for sale to purchasers, without regard to whether such person is or has been primarily engaged in such business.
21 CFR 1000.3(h)	*Distributor* means a person engaged in the business of offering electronic products for sale to dealers, without regard to whether such person is or has been primarily or customarily engaged in such business.
21 CFR 1301.11(a)	Every person who manufactures, distributes, dispenses, imports, or exports and controlled substance or who proposes to engage in the manufacture, distribution, dispensing, importation or exportation of any controlled substance shall obtain a registration unless exempted by law…

*Reference is to the Federal Food, Drug and Cosmetic Act (by "Section") or to Code of Federal Regulations ("CFR")

Exhibit III: Existing Regulations, Medical Device Reporting

Reference*	Regulation
Section 519(a)(1)	Regulations prescribed under the preceding sentence-- (1) shall require a device manufacturer or importer to report to the Secretary whenever the manufacturer or importer receives or otherwise becomes aware of information that reasonably suggests that one of its marketed devices-- (B) may have caused or contributed to a death or serious injury, or (c) has malfunctioned and that such device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur;... ...The Secretary shall by regulation require distributors to keep records and make such records available to the Secretary upon request.
21 CFR 211.198(a)	Written procedures describing the handling of all written and oral complaints regarding a drug product shall be established and followed.
21 CFR 606.170(a)	Records shall be maintained of any reports of complaints of adverse reactions regarding each unit of blood or blood product...
21 CFR 803.1(a)	Medical device distributors, as defined in § 803.3, are also required to maintain records of incidents (files).
21 CFR 803.19(d)	(1) A device distributor shall establish and maintain device complaint records containing any incident information, including any written, electronic, or oral communication, either received by or generated by the firm, that alleges deficiencies related to the identity (e.g., labeling), quality, durability, reliability, safety, effectiveness, or performance of a device...

*Reference is to the Federal Food, Drug and Cosmetic Act (by "Section") or to Code of Federal Regulations ("CFR")

Exhibit IV: Existing Regulations. Medical Device Tracking

Reference*	Regulation
Section 519(e)(1)	The Secretary may by order require a manufacturer to adopt a method of tracking a class II or class III device--- (B) the failure of which would be reasonably likely to have serious adverse health consequences; or (C) which is--- (1) intended to be implanted in the human body for more than one year, or (2) a life sustaining or life-supporting device used outside a device user facility.
21 CFR 821.1	The regulations in this part implement section 519(e) of the Federal Food, Drug and Cosmetic Act (the act) which requires the adoption of a method of device tracking by any person who registers under section 510 of the act and is engaged in the manufacture and distribution of devices the failure of which would be reasonably likely to have serious adverse health consequences if the devices are life-sustaining or life-supporting devices used outside of a device user facility or are permanently implantable devices.
21 CFR 821.30(a)	A distributor, final distributor, or multiple distributor of any tracked device shall, upon purchasing or otherwise acquiring any interest in such a device, promptly provide the manufacturer tracking the device with the following information...

*Reference is to the Federal Food, Drug and Cosmetic Act (by "Section") or to Code of Federal Regulations ("CFR")

Exhibit V: Existing Regulations, Records and Reports

Reference*	Regulation
Section 519(c)	Subsection (a) shall not apply to--... (3) any other class of persons as the Secretary may by regulation exempt from subsection (a) of this section upon a finding that compliance with the requirements of such subsection by such class with respect to a device is not necessary to (A) assure that a device is not adulterated or misbranded or (B) otherwise to assure its safety and effectiveness.
21 CFR 205.50(f)	Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs.
21 CFR 211.196	Distribution records shall contain the name and strength of the product and description of the dosage form, name and address of the consignee, date and quantity shipped. And lot or control number of the drug product.
21 CFR 606.165(b)	Distribution records shall contain information to readily facilitate the identification of the name and address of the consignee, the date and quantity delivered, the lot number...
21 CFR 1002.40(a)	Dealers and distributors of electronic products for which there are performance standards and for which the retail price is $50 or more shall obtain such information as is necessary to identify and locate first purchasers...
21 CFR 1304.03(a)	Each registrant shall maintain the records and inventories required by this part, except as exempted by this section.
21 CFR 1310.03(a)	Each regulated person who engages in a regulated transaction involving a listed chemical, a tableting machine, or an encapsulating machine shall keep a record of the transaction as specified by §1310.04 and file reports as specified by §1310.05

*Reference is to the Federal Food, Drug and Cosmetic Act (by "Section") or to Code of Federal Regulations ("CFR")

Exhibit VI: Compliance, Chemdex Supplier Agreement

"4.2 Regulatory Compliance.

Supplier agrees, represents, and warrants that it will comply with all applicable laws, regulations, rules, requirements, and ordinances of governmental or other agencies applicable to the sale, distribution, transportation, exportation, or importation of Products under this Agreement. In particular, but without limitation, the Supplier agrees, warrants and represents that it will obtain all required licenses, permits, and approvals from the appropriate government and other agencies necessary to sell, distribute, transport, export, and import the Products to any Customer under this Agreement; that it is fully aware of all applicable governmental rules and regulations; that it will prepare and maintain any records or documentation regarding sales, distribution, transportation, exportation, or importation required by governmental or other agencies; and that it will ensure that the packaging and labeling, and the transportation method and carrier chosen are appropriate for each Product. Supplier agrees to provide lists to Chemdex upon request and in a reasonable time frame of all Products it sells that require either Supplier or Customers to possess governmental or other licenses, permits, or approvals, or that require special recordkeeping. Supplier further agrees that it will sign the agreements and other documents provided by the various carrier companies relating to transportation. Supplier agrees, represents, and warrants that it will (a) verify that Customer possesses the necessary licenses, permits, approvals, qualifications, and knowledge necessary to purchase and properly use each Product sold under this Agreement; (b) provide Product only to Customers and end-users that are authorized to receive and use such Product under applicable laws, regulations, rules, and ordinances; and (c) provide Product only in compliance with all approvals and restrictions imposed by appropriate government and other agencies; (d) notify Chemdex in a timely manner of any investigations or inquiries from governmental regulatory agencies or claims by third parties concerning the sale, distribution, transportation, exportation, or importation of the Product.

4.3 Compliance with FDA Requirements.

In addition to the requirements of several federal, state and local governmental agencies, Supplier acknowledges that the Food and Drug Administration ("FDA") imposes certain regulations on Products intended for human or veterinary uses. Supplier agrees, represents and warrants that it will also comply with all applicable FDA requirements, including but not limited to those concerning marketing clearance or approval, manufacturing, packaging, labeling, advertising, off-label uses and promotion. Supplier further agrees, represents, and warrants that it will comply with all applicable record keeping and record retention requirements, including but not limited to those concerning registration, production records, medical products listing, medical device tracking, medical products reporting (MedWatch), complaint files, adverse events, and recall information. Supplier agrees, represents, and warrants that it will ensure that the packaging, labeling, transportation method, and the carrier chosen are appropriate for each Product. Supplier further agrees, warrants, and represents that all advertising and promotional statements provided to Chemdex (whether for use on the Chemdex website or for internal Chemdex use) comply with FDA requirements and the requirements of other regulatory agencies, as applicable. Supplier agrees, represents and warrants that it will notify Chemdex promptly of any revisions in such statements that should be made in order to maintain compliance with these requirements. Supplier further agrees, warrants and represents that they shall meet the requirements designed to assure that all purchases and uses of Products intended for human or veterinary use (including, but not limited to prescription devices, in vitro diagnostic products, licensed biologicals, analyte specific reagents, restricted devices, investigational devices, and significant risk devices) are appropriate under applicable FDA, Medicare, and other laws and regulations. If Supplier or Chemdex learns of Customers that are using the Products outside of their intended uses, Supplier, in the case of Supplier discovery and Chemdex in the case of Chemdex discovery, shall immediately cease further shipments to the Customer and notify the other party of such action.

4.4 Product Recalls.

Supplier agrees, represents, and warrants that (a) all responsibilities (including but not limited to regulatory, medical, legal, and financial) related to the recall of any of its Products are the responsibility of

the Supplier; (b) if any Products sold by the Supplier are the subject of a Product Recall, Supplier will immediately inform Chemdex, and Supplier will take all steps necessary to inform Chemdex Customers of such recall; (c) Supplier will notify Chemdex in a timely manner of any investigations or inquiries from U.S. or foreign governmental regulatory agencies concerning the sale, distribution, transportation, and recall of the Products; (e) Supplier will provide Chemdex in a timely manner with copies of all such documents that pertain to any government action, inquiry, or investigation of Products that are listed by Chemdex; and (e) Supplier shall keep Chemdex fully informed of any actions taken by such agencies that may reasonably be expected to have a negative impact on the sale or availability of the Products and will provide Chemdex with copies of all documentation of government action that pertains to Chemdex Products."

Exhibit VII: Compliance, Promedix Supplier Agreement

"**4.1 Regulatory Compliance.** Supplier agrees, warrants and represents that it will comply with all applicable laws, regulations, rules, requirements, and ordinances of governmental or other agencies applicable to the sale, distribution, transportation, exportation, or importation of Products under this Agreement. In particular, Supplier agrees, warrants and represents that it will: maintain all licenses, permits, and other approvals necessary to sell, distribute, transport, export, import and ship the Products; pack and ship the Products only to authorized purchasers and end-users at authorized locations in accordance with all applicable laws and regulations (including those regarding the export of Products or technology abroad); comply with all applicable FDA requirements, including but not limited to those concerning labeling, advertising, off-label uses, promotion, tracking and reporting and record keeping (e.g. complaints, adverse reactions, recall information); ensure that the packaging and labeling, and transportation method and carrier chosen are appropriate for each Product; ensure that all purchases and uses of prescription devices are appropriate under applicable FDA, Medicare, and other laws and regulations; and obtain all marketing clearances and/or approvals that may be required for applicable Products prior to the sale of such Products by Promedix. If Supplier learns of Customers that are using the Products outside of their intended uses, Supplier shall immediately cease further shipments to the Customer and notify Promedix of such activities.

4.2 Customer Qualification. Supplier agrees, warrants and represents that Supplier a) will verify that Customers possess the necessary licenses, permits, approvals, qualifications, and knowledge necessary to purchase and properly use each Product sold under this Agreement; b) will provide Products only to Customers and end-users that are authorized to receive and use such Products under applicable laws and regulations (including without limitation those regarding the export of Products or technology abroad); and c) will provide Products only in compliance with all approvals and restrictions imposed by appropriate government and other agencies.

4.3 Record Retention and Compliance. Supplier agrees, warrants and represents that the Supplier is in compliance with all regulatory agency requirements regarding all documentation pertaining to registration, adverse event and complaint reporting, device tracking, manufacturing batch records, labeling, advertising, and quality system requirements, as a distributor or as a manufacturer. Supplier also agrees, warrants and represents that it will maintain all records of such regulatory compliance for the useful life (as defined by FDA) of all Products. All compliance records will be maintained for the length of time specified by the relevant agencies even if the Supplier should discontinue some Products.

4.4 Product Returns and Recalls. Promedix shall assist Supplier with the return of Products from the Customer to the Supplier and will assist Supplier in resolving any Product disputes associated with Product returns. Product returns are subject to any warranty claims Promedix may assert against Supplier as a result of such returns. Supplier agrees, warrants and represents that: (a) all responsibilities (including but not limited to regulatory, medical, legal and financial) related to the recall of any Product are the responsibility of the Supplier; b) if any Products sold by Supplier are the subject of a Product recall, Supplier will immediately inform Promedix in writing, and Supplier will take all steps necessary to inform Promedix Customers of such recall; c) Supplier will promptly notify Promedix in writing of any investigations or inquiries from U.S. or foreign governmental regulatory agencies concerning the sale, distribution, transportation that pertain to the recall of the Products; d) Supplier will provide Promedix in a prompt manner with copies of all such documents that pertain to any government action, inquiry, or investigation of Products that are listed by Promedix; and e) Supplier shall keep Promedix fully informed of any actions taken by such agencies that may reasonably be expected to have a negative impact on the sale or availability of the Products and will provide Promedix with copies of all documentation of government action that pertains to Promedix Products.

4.5 Federal Health Program. Supplier represents and warrants that it is not ineligible to participate in "Federal Health Care Program" as defined in 42 U.S.C. Section 1320a-7b(f) (or any applicable successor statutory section) or in any other government payment program. In the event Supplier is excluded from participation, or becomes otherwise ineligible to participate in any such program, Supplier shall notify Promedix in writing within three (3) days after such event, and upon the occurrence of such event, whether or not such notice is given to Promedix, Promedix may immediately terminate the whole or any part of a purchase order with Supplier."

Exhibit VIII: Compliance, Chemdex Customer Agreement

"Use Restrictions.
All use by Customer and Users of the Chemdex System, and all purchases of Products, shall be subject to the terms and conditions set forth in this Agreement and the guidelines outlined in Exhibit B ("Regulatory Addendum").
Customer agrees, represents and warrants that Products will be used only for the indications and applications specified on the Product labeling and that Products will be used properly, reasonable, safely, and as intended. Customer agrees, represents and warrants that Products will be used for research use only and will not be used for human, animal, therapeutic, or diagnostic use, or for the treatment of animals, as that term is defined by the U. S. Department of Agriculture; that any explosives regulated by the Bureau of Alcohol, Tobacco, and Firearms will only be used as industrial and chemical products intended for use as reagents; and that it will not resell at wholesale any distilled spirits Products to a wholesaler or retailer. Customer agrees, warrants, and represents that it will only use Products regulated by the Toxic Substances Control Act (TSCA) for research and development, in small quantities not greater than reasonably necessary for research and development activities. Customer further agrees, represents, and warrants that it recognizes that certain Chemdex Products are regulated by the Food and Drug Administration (FDA) and that these Products may have additional use restricts, or limited uses, that must be adhered to for compliance to FDA regulations.

2.2 Compliance with Laws.

Customer agrees, represents and warrants that it will comply with all applicable laws, regulations, rules, requirements, and ordinances of governmental or other agencies applicable to the sale, distribution, transfer, transportation, exportation, importation, handling, disposal, processing, or use (hereafter collectively referred to as "Use") of the Products under this Agreement. In particular, but without limitation, the Customer agrees, warrants and represents that it will obtain, maintain, and comply with all required licenses, permits, and approvals from the appropriate government and other agencies necessary to purchase or Use the Products; that it is fully aware of all applicable governmental rules and regulations; that it will assure that all persons who purchase or Use the Products are fully authorized and qualified to do so; and, that it will prepare and maintain any records, reports, or documentation regarding the purchase or Use of the Products required by governmental or other agencies.
Customer agrees, represents, and warrants that it will serve as and fulfill all obligations as the importer of any Products, if such Products are considered to be imports by any governmental authority. In no event will Chemdex serve as importer or fulfill any importation obligations. Customer agrees, represents, and warrants that it will provide Chemdex, and the Supplier of Product if applicable, evidence of appropriate licenses, permits, approvals, or other records required to purchase or Use the Product, if requested to provide such evidence."

Exhibit IX: Regulatory Addendum, Chemdex Customer Agreement

"EXHIBIT B
REGULATORY ADDENDUM

A. INTRODUCTION. Following are brief summaries of some of the federal and selected state regulatory requirements that relate to sales, through the Chemdex website, of materials, devices, and equipment (Products). These summaries are not exhaustive of the applicable requirements governing Internet sales, and are intended to alert the Purchaser but not to provide legal advice regarding its obligations. Only selected Federal and California Proposition 65 requirements have been abstracted, and not other state or local requirements, or requirements that may be imposed by other countries. Purchaser is expected to comply fully with all applicable Federal, state, and local rules, regulations, and requirements. For a variety of reasons, Chemdex has elected to exclude from its website the sale of certain Products controlled by regulatory agencies, or has decided not to export or import them. The full texts of the applicable federal and state requirements should be consulted for their precise terms and conditions. Such information for each governmental agency can be found on the agency's website, referenced below.

B. DRUG ENFORCEMENT ADMINISTRATION (DEA, www.usdoj.gov/dea**).** The only DEA Controlled Substances currently being sold on the Chemdex website are those on DEA List II; no Schedule I-V or List I Substances is sold. Chemdex relies upon Purchaser to maintain necessary records, submit any necessary reports, and not purchase List II substances in a quantity or manner indicative of a violation of applicable regulations. See 21 CFR, Part 1310. Chemdex does not sell any Scheduled or Listed Substances for exportation or importation. See 21 CFR, Parts 1300-1308.

C. NUCLEAR REGULATORY COMMISSION (NRC, www.nrc.gov**).** Chemdex relies upon Purchaser to comply with all applicable requirements regarding the purchase and use of products regulated by the NRC and its state counterparts, including, without limitation, those relating to any medical uses of the products. See 42 U.S.C. 2111, et seq. And 10 CFR, Part 1, et seq.

D. CHEMICAL AND BIOLOGICAL WEAPONS (CBW, www.bxa.doc.gov). Chemdex relies upon Purchaser to comply with all applicable requirements regarding these materials, including (without limitation) to ensure that materials regulated as chemical or biological agents, toxins, or their components will be used for peaceful purposes, such as scientific research, and not for use as weapons. See 22 U.S.C. 6701-677, 18 U.S.C. 178, et. seq., 15 CFR, Parts 734-7741. Chemdex does not sell Schedule 1 chemicals but does offer for sale chemicals listed on Schedules 2 and 3. Chemdex does not offer these materials for exportation or importation. Chemdex offers for sale certain Etiological Agents but does not offer those biological products known as Select Agents. Chemdex relies upon Purchaser to comply with all applicable regulations regarding the purchase and use of any of these materials.

E. CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC, www.cdc.gov**).** Chemdex does not sell substances listed as Select Agents by the CDC. See 42 CFR, Part 72, Appendix A. Chemdex does, however, sell Etiologic Agents, as defined by CDC, and relies upon Purchaser to comply with all applicable requirements relating to the purchase and use of those Agents. See 42 CFR, Part 72.

F. PROPOSITION 65 (www.oehha.org/Prop65**).** Chemdex relies upon Supplier and Purchaser to see that all required warnings are provided and relies upon Purchaser to see that all Products are handled, used, and disposed in manners consistent with their properties, including any potential to cause cancer, reproductive toxicity, or any other harm, damage, or injury.

G. BUREAU OF ALCOHOL, TOBACCO, AND FIREARMS (ATF, www.atf.treas.gov**).**

1. **Alcohol.** Chemdex relies upon Purchaser to ensure that denatured and non-denatured alcohol is used exclusively for non-beverage, scientific research and development purposes, and that it is bought only for Purchaser's own use, and not for resale to others. Purchaser should also possess a valid permit from ATF to purchase specially denatured alcohol, and should provide a photocopy of that permit to Supplier before such alcohol is shipped. Chemdex relies upon Purchaser to comply with all applicable requirements regarding alcohol, including (without limitation) those relating to handling, record keeping, storage, taxes, and tax-free purchases.
2. **Explosives.** Chemdex only sells Products exempted by the ATF from its regulations governing explosives. Products are exempt if they are industrial and laboratory chemicals intended for use as reagents, and if Department of Transportation explosives hazard warning labels are not required for their shipment. Chemdex relies upon Purchaser to ensure that these requirements are met.

H. ENVIRONMENTAL PROTECTION AGENCY (EPA).

1. Ozone (www.epa.gov/ozone). Chemdex does not sell Class I Ozone-Depleting substances, which have been or are scheduled, in the near future, to be deleted from the inventory of substances that may legally be sold. Chemdex also does not sell HCFC-141b, because of an accelerated phase-out by EPA, nor does it sell substances found to be unacceptable substitutes under the Significant New Alternatives Policy (SNAP). Selected Class II substances are offered for sale. Purchaser should verify the status of any chemicals, and any use limitations, which may be regulated under the SNAP program (see 40 CFR 82 Subpart G). Chemdex relies upon Purchaser to comply with all applicable regulations regarding the purchase and use of any of these materials.

2. Toxic Substances Control Act (TSCA, www.epa.gov/opptintr/index.html). Chemdex relies upon Purchaser to comply with the requirements of TSCA, along with all other regulations relating to potentially toxic and hazardous substances. For example, Chemdex relies upon Purchaser to ensure that chemical substances regulated by TSCA are used for research and development, and purchased in small quantities not greater than reasonably necessary for those uses. Chemdex does not sell polychlorinated biphenyls (PCBs) or asbestos-containing materials regulated by TSCA.

I. FOOD AND DRUG ADMINISTRATION (FDA, www.fda.gov**).**

Chemdex offers for sale Products that are regulated by the FDA. Some of these Products are designated by the FDA as for "Research Use Only" and are not intended for the treatment of animals or humans (See 21 CFR definition of "treatment"). Chemdex relies upon Purchaser not to alter labels on the products they have purchased, or to otherwise misuse the products outside of their intended uses.

Purchaser acknowledges that for those FDA-regulated Products that are designated for human or veterinary use (including but not limited to biologicals, pharmaceuticals, prescription devices, in vitro diagnostic products, analyte specific reagents, restricted devices, investigational devices, and significant risk devices) the purchaser may be required to file and maintain all FDA-required documents relative to the sale of medical devices, such as adverse events, complaints, medical device tracking, and product recalls. Purchaser also acknowledges that certain additional regulations may be applicable to such products, including without limitation, compliance to labeling, advertising, and off- label use regulations, compliance to record keeping and record retention requirements, and the maintenance of certain types of records (e.g., registration, device tracking, device reports, complaint files, adverse events, and product recalls).

J. OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION (OSHA, www.osha.gov**).** Chemdex relies upon suppliers to make available to Purchaser appropriate Material Safety Data Sheets in accordance with OSHA regulations and to ensure that appropriate labels are affixed to Products with all required OSHA information. See 29 CFR 1910.1200. If such MSDS and labels are not provided, Purchaser should contact the supplier and obtain them. Chemdex relies upon Purchaser to make the requisite MSDS and labels available to its employees who may be handling the Products.

K. DEPARTMENT OF AGRICULTURE (USDA, www.usda.gov**).** Chemdex offers for sale certain USDA-regulated Products that are designated "For Research Use Only" and are intended only for research purposes, and are not intended for human or animal therapeutic, pharmaceutical, or diagnostic uses or treatment, as defined by USDA. Licensed biologics intended for human or veterinary use may have additional requirements, regulations, and restrictions. Chemdex relies upon Purchaser to ensure compliance with these use restrictions, and to obtain and maintain necessary licenses, permits (exportation and other), and authorizations, and satisfy all other applicable requirements. See 21 CFR Subchapter E."

Exhibit X: Compliance, Promedix Customer Agreement

"Use Restrictions.
All use by Customer and Users of the Promedix System, and all purchases of Products, shall be subject to the terms and conditions set forth in this Agreement and the guidelines outlined in Exhibit B ("Regulatory Addendum").
Customer agrees, represents and warrants that Products will be used only for the indications and applications specified on the Product labeling and that Products will be used properly, reasonable, safely, and as intended. Customer further agrees, represents, and warrants that it recognizes that certain Promedix Products are regulated by the Food and Drug Administration (FDA) and that these Products may have additional use restricts, or limited uses, that must be adhered to for compliance to FDA regulations.

2.2 Compliance with Laws.

Customer agrees, represents and warrants that it will comply with all applicable laws, regulations, rules, requirements, and ordinances of governmental or other agencies applicable to the sale, distribution, transfer, transportation, exportation, importation, handling, disposal, processing, or use (hereafter collectively referred to as "Use") of the Products under this Agreement. In particular, but without limitation, the Customer agrees, warrants and represents that it will obtain, maintain, and comply with all required licenses, permits, and approvals from the appropriate government and other agencies necessary to purchase or Use the Products; that it is fully aware of all applicable governmental rules and regulations; that it will assure that all persons who purchase or Use the Products are fully authorized and qualified to do so; and, that it will prepare and maintain any records, reports, or documentation regarding the purchase or Use of the Products required by governmental or other agencies.
Customer agrees, represents, and warrants that it will serve as and fulfill all obligations as the importer of any Products, if such Products are considered to be imports by any governmental authority. In no event will Promedix serve as importer or fulfill any importation obligations. Customer agrees, represents, and warrants that it will provide Promedix, and the Supplier of Product if applicable, evidence of appropriate licenses, permits, approvals, or other records required to purchase or Use the Product, if requested to provide such evidence."

Exhibit XI: Regulatory Addendum, Promedix Customer Agreement

"EXHIBIT B
REGULATORY ADDENDUM

A. **INTRODUCTION.** Following are brief summaries of some of the federal regulatory requirements that relate to sales, through the Promedix website, of materials, devices, and equipment (Products). These summaries are not exhaustive of the applicable requirements governing Internet sales, and are intended to alert the Purchaser but not to provide legal advice regarding its obligations. Only selected Federal requirements have been abstracted, and not other state or local requirements, or requirements that may be imposed by other countries. Purchaser is expected to comply fully with all applicable Federal, state, and local rules, regulations, and requirements. For a variety of reasons, Promedix has elected to exclude from its website the sale of certain Products controlled by regulatory agencies, or has decided not to export or import them. The full texts of the applicable federal and state requirements should be consulted for their precise terms and conditions. Such information for each governmental agency can be found on the agency's website, referenced below.

B. **DRUG ENFORCEMENT ADMINISTRATION (DEA,** www.usdoj.gov/dea**).** Promedix currently does not offer products for sale that are on DEA Schedules I-V or on List Promedix relies upon Purchaser to maintain necessary records, submit any necessary reports, and not purchase List II substances in a quantity or manner indicative of a violation of applicable regulations. See 21 CFR, Part 1310. Promedix does not sell any Scheduled or Listed Substances for exportation or importation. See 21 CFR, Parts 1300-1308.

C. **NUCLEAR REGULATORY COMMISSION (NRC,** www.nrc.gov**).** Promedix relies upon Purchaser to comply with all applicable requirements regarding the purchase and use of products regulated by the NRC and its state counterparts, including, without limitation, those relating to any medical uses of the products. See 42 U.S.C. 2111, et seq. And 10 CFR, Part 1, et seq.

D. **CHEMICAL AND BIOLOGICAL WEAPONS (CBW,** www.bxa.doc.gov). Promedix relies upon Purchaser to comply with all applicable requirements regarding these materials, including (without limitation) to ensure that materials regulated as chemical or biological agents, toxins, or their components will be used for peaceful purposes, such as scientific research, and not for use as weapons. See 22 U.S.C. 6701-677, 18 U.S.C. 178, et. seq., 15 CFR, Parts 734-7741. Promedix does not offer for sale chemicals listed on Schedules 1, 2 or 3. Promedix offers for sale certain Etiological Agents but does not offer those biological products known as Select Agents. Promedix relies upon Purchaser to comply with all applicable regulations regarding the purchase and use of any of these materials.

E. **CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC,** www.cdc.gov**).** Promedix does not sell substances listed as Select Agents by the CDC. See 42 CFR, Part 72, Appendix A. Promedix does, however, sell Etiologic Agents, as defined by CDC, and relies upon Purchaser to comply with all applicable requirements relating to the purchase and use of those Agents. See 42 CFR, Part 72.

F. **BUREAU OF ALCOHOL, TOBACCO, AND FIREARMS (ATF,** www.atf.treas.gov**).**
Promedix relies upon Purchaser to ensure that denatured and non-denatured alcohol is used exclusively for non-beverage, scientific research and development purposes, and that it is bought only for Purchaser's own use, and not for resale to others. Purchaser should also possess a valid permit from ATF to purchase specially denatured alcohol, and should provide a photocopy of that permit to Supplier before such alcohol is shipped. Promedix relies upon Purchaser to comply with all applicable requirements regarding alcohol, including (without limitation) those relating to handling, record keeping, storage, taxes, and tax-free purchases.

G. **FOOD AND DRUG ADMINISTRATION (FDA,** www.fda.gov**).**
Promedix offers for sale Products that are regulated by the FDA. Some of these Products are designated by the FDA as for "Research Use Only" and are not intended for the treatment of animals or humans (See 21 CFR definition of "treatment"). Promedix relies upon Purchaser not to alter labels on the products they have purchased, or to otherwise misuse the products outside of their intended uses.
Purchaser acknowledges that for those FDA-regulated Products that are designated for human or veterinary use (including but not limited to biologicals, pharmaceuticals, prescription devices, in vitro diagnostic products, analyte specific reagents, restricted devices, investigational devices, and significant risk devices) the purchaser may be required to file and maintain all FDA-required documents relative to the sale of medical devices, such as adverse events, complaints, medical device tracking, and product recalls. Purchaser also acknowledges that certain additional regulations may be applicable to such products, including without limitation, compliance to labeling, advertising, and off- label use regulations,

compliance to record keeping and record retention requirements, and the maintenance of certain types of records (e.g., registration, device tracking, device reports, complaint files, adverse events, and product recalls).

H. **OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION (OSHA,** www.osha.gov**).** Promedix relies upon suppliers to make available to Purchaser appropriate Material Safety Data Sheets in accordance with OSHA regulations and to ensure that appropriate labels are affixed to Products with all required OSHA information. See 29 CFR 1910.1200. If such MSDS and labels are not provided, Purchaser should contact the supplier and obtain them. Promedix relies upon Purchaser to make the requisite MSDS and labels available to its employees who may be handling the Products.

I. **DEPARTMENT OF AGRICULTURE (USDA,** www.usda.gov**).** Promedix offers for sale certain USDA-regulated Products that are designated "For Research Use Only" and are intended only for research purposes, and are not intended for human or animal therapeutic, pharmaceutical, or diagnostic uses or treatment, as defined by USDA. Licensed biologics intended for human or veterinary use may have additional requirements, regulations, and restrictions. Promedix relies upon Purchaser to ensure compliance with these use restrictions, and to obtain and maintain necessary licenses, permits (exportation and other), and authorizations, and satisfy all other applicable requirements. See 21 CFR Subchapter E."

Exhibit XII: Chemdex Terms & Conditions (Use Restrictions)

"Buyer agrees, represents and warrants that Products will be used only for the indications and applications specified on the Product labeling and that Products will be used properly, reasonably, safely, and as intended. Promedix relies upon Buyer not to alter labels on the products they have purchased, or to otherwise misuse the products outside of their intended uses. For some products, the Buyer may be required to file and maintain all FDA-required documents relative to the sale of medical devices, such as device adverse events, device complaints, medical device tracking, and product recalls."

Exhibit XIII: Chemdex Terms & Conditions (Compliance with Laws)

"Buyer agrees, represents and warrants that it will comply with all applicable laws, regulations, rules, requirements, and ordinances of governmental or other agencies applicable to the sale, distribution, transfer, transportation, exportation, importation, handling, disposal, processing or use (hereafter sometimes collectively referred to as "Use") of the Products under this Agreement. In particular, but without limitation, the Buyer agrees, warrants and represents that it will obtain, maintain, and comply with all required licenses, permits, and approvals from the appropriate government and other agencies necessary to purchase or Use the Products; that it is fully aware of all applicable governmental rules and regulations; that it will assure that all persons who purchase or Use the Products are fully authorized and qualified to do so; and, that it will prepare and maintain any records, reports, or documentation regarding the purchase or Use of the Products required by governmental or other agencies."

Exhibit XIV: Promedix Terms & Conditions (Use Restrictions)

"Buyer agrees, represents and warrants that Products will be used only for the indications and applications specified on the Product labeling and that Products will be used properly, reasonably, safely, and as intended. Buyer acknowledges that the Products may not have been tested for safety and efficacy in food, drug, medical device, cosmetic, commercial or any other use. Products may contain chemicals that may be harmful if misused. Customer shall exercise due care with all Products. Only qualified, trained professionals who are familiar with the hazards associated with such Products should handle all Products.

Promedix relies upon Buyer not to alter labels on the products they have purchased, or to otherwise misuse the products outside of their intended uses. For some products, the Buyer may be required to file and maintain all FDA-required documents relative to the sale of medical devices, such as device adverse events, device complaints, medical device tracking, and product recalls."

Exhibit XV: Promedix Terms & Conditions (Compliance with Laws)

"Buyer agrees, represents and warrants that it will comply with all applicable laws, regulations, rules, requirements, and ordinances of governmental or other agencies applicable to the sale, distribution, transfer, transportation, exportation, importation, handling, disposal, processing, or use (hereafter sometimes collectively referred to as "Use") of the Products under these Terms.

In particular, but without limitation, the Buyer agrees, warrants and represents that it will obtain, maintain, and comply with all required licenses, permits, and approvals from the appropriate government and other agencies necessary to purchase or Use the Products; that it is fully aware of all applicable governmental rules and regulations; that it will assure that all persons who purchase or use the Products are fully authorized and qualified to do so; and, that it will prepare and maintain any records, reports, or documentation regarding the purchase or Use of the Products required by governmental or other agencies.

Buyer agrees, represents, and warrants that it will serve as and fulfill all obligations as the importer of any Products, if such Products are considered to be imports by any governmental authority. In no event will Promedix serve as importer or fulfill any importation obligations.

Buyer agrees, represent, and warrant that it will provide Promedix, and the Supplier of Product if applicable, evidence of appropriate licenses, permits, approvals, or other records required to purchase or Use the Product, if requested to provide such evidence."

Exhibit XVI: Agency Definitions

Agency	Reference	Definition
ATF	27 CFR 194.11	Dealer: Any person who sells, or offers for sale, any distilled spirits, wines, or beer.
ATF	27 CFR 55.11	Dealer: Any person engaged in the business of distributing explosive materials at wholesale or retail
ATF	27 CFR 55.11	Distribute: To sell, issue, give, transfer, or otherwise dispose of. The term does not include a mere change of possession from a person to his agent or employee in connection with the agency or employment.
DEA	21 CFR 1300.01(41)	Supplier: means any registered person entitled to fill order forms pursuant to §1305.08 of this chapter
DEA	21 CFR 1300.02	The term *broker* and *trader* mean any individual, corporation, corporate division, partnership, association, or other legal entity which assists in arranging an international transaction in a listed chemical...
DEA	21 USC 802	Agent: ...an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser...
DEA	21 USC 802	Distribute: ...to deliver (other than by administering or dispensing) a controlled substance or listed chemical.
DEA	21 USC 802	Distributor: ...a person who so delivers a controlled substance or listed chemical.
EPA	15 USC 2602	The term "distribute in commerce" and "distribution in commerce" ...means to sell, or the sale of, the substance, mixture, or article in commerce; to introduce or deliver for introduction or delivery for introduction into commerce of, the substance, mixture, or article; or to hold, or the holding of, the substance, mixture, or article after its introduction into commerce.
USDA	9 CFR 1.1	Dealer: any person who, in commerce, for compensation or profit, delivers for transportation, or transports, except as a carrier, buys, or sells, or negotiates the purchase or sale of...
USDA	9 CFR 101.2	Distributor: A person who sells, distributes, or otherwise places in channels of trade, one or more biological products he does not produce or import.
DOL	29 CFR 1200(c)	Distributor: ...a business, other than a chemical manufacturer or importer, which supplies hazardous chemicals to other distributors or to employers.